Once Daily Etravirine in Treatment-Naïve Adults
08-2070 Trial
Once Daily Etravirine in Treatment-Naïve Adults 08-2070: Design

**Study Design: 08-2070**

- **Background**: Phase 2, single-arm trial assessing activity, safety, and tolerability of once-daily etravirine with tenofovir DF-emtricitabine in treatment-naïve adults with HIV infection

- **Inclusion Criteria (n = 79)**
  - Age ≥18
  - HIV RNA >1000 copies/mL
  - Treatment-naïve
  - No resistance to etravirine or TDF-FTC

- **Treatment Arms**
  - Etravirine 400 mg QD + tenofovir-emtricitabine QD

*ITT: Intent-to-Treat, M=F: missing equals failure

Once Daily Etravirine in Treatment-Naïve Adults 08-2070: Result

Week 48: Virologic Response (all patients taking ETR + TDF-FTC)

HIV RNA <50 copies/mL (%)

ITT, M=F* | As Treated
---|---
<50 copies/mL: 61/79 | 61/69 | 77
<200 copies/mL: 65/79 | 65/69 | 88

*ITT: Intent-to-Treat, M=F: missing equals failure

Once Daily Etravirine in Treatment-Naïve Adults 08-2070: Result

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rash (any grade)</td>
<td>5 (6.3)</td>
</tr>
<tr>
<td>Any grade 2 or higher event</td>
<td>18 (22.8)</td>
</tr>
<tr>
<td>New/worsened grade 3 or 4 sign/symptom</td>
<td>10 (12.7)</td>
</tr>
<tr>
<td>AST or ALT elevation (Grade 2 or higher)</td>
<td>5 (6.3)</td>
</tr>
<tr>
<td>Grade 2 creatinine elevation</td>
<td>2 (2.5)</td>
</tr>
<tr>
<td>New/worsened grade 3 or 4 laboratory abnormality</td>
<td>6 (7.6)</td>
</tr>
<tr>
<td>Etravirine discontinued due to toxicity</td>
<td>3 (3.8)</td>
</tr>
</tbody>
</table>

**Conclusions**: “In this study of ARV-naive HIV-positive adults, once-daily ETR with TDF/FTC had acceptable antiviral activity and was well-tolerated. Once-daily ETR may be a plausible option as part of a combination ARV regimen for treatment-naive individuals.”

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